Dated: September 15, 1995.

Janice F. Oliver,

Deputy Director for Systems and Support, Center for Food Safety and Applied Nutrition.

[FR Doc. 95–23598 Filed 9–22–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Ketamine Injection

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Fermenta Animal Health Co. The ANADA provides for intramuscular use of ketamine hydrochloride injection in cats for restraint and to produce anesthesia that is suitable for diagnostic or minor surgical procedures that do not require skeletal muscle relaxation and in nonhuman primates for restraint.

EFFECTIVE DATE: September 25, 1995.

FOR FURTHER INFORMATION CONTACT: Sandra K. Woods, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1616.

SUPPLEMENTARY INFORMATION: Fermenta Animal Health Co., P.O. Box 338, 15th and Oak Sts., Elwood, KS 66024, filed ANADA 200–029, which provides for intramuscular use of ketamine hydrochloride injection (equivalent to 100 milligrams/milliliter (mg/mL) ketamine) in cats for restraint and to produce anesthesia that is suitable for diagnostic or minor surgical procedures that do not require skeletal muscle relaxation and in nonhuman primates for restraint. The drug is limited to use by or on the order of a licensed veterinarian.

Fermenta Animal Health's ANADA 200–029 for ketamine hydrochloride injection (equivalent to 100 mg/mL ketamine) is approved as a generic copy of Fort Dodge Laboratories' NADA 045–290 for Vetalar® /Ketaset® (ketamine hydrochloride injection equivalent to 100 mg/mL ketamine). The ANADA is approved as of August 16, 1995, and the regulations are amended in 21 CFR 522.1222a(c) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, § 522.1222a is amended by removing and reserving paragraphs (a) and (d).

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20855, from 9 a.m. to 4 p.m., Monday through Friday.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above), between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. Section 522.1222a is amended by removing and reserving paragraphs (a) and (d), and by revising paragraph (c) to read as follows:

§ 522.1222a Ketamine hydrochloride injection.

(a) [Reserved]

* * * * *

(c) *Sponsors.* See Nos. 000856, 045984, 054273, and 057319 in § 510.600(c) of this chapter.

(d) [Reserved]

* * * * *

Dated: September 8, 1995.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 95–23600 Filed 9–22–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Melarsomine Dihydrochloride for Injection

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Rhone Merieux, Inc. The NADA provides for intramuscular use of injectable melarsomine dihydrochloride for the treatment of heartworm disease in dogs.

EFFECTIVE DATE: September 25, 1995.

FOR FURTHER INFORMATION CONTACT: Marcia K. Larkins, Center for Veterinary Medicine (HFV–112), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0137.

SUPPLEMENTARY INFORMATION: Rhone Merieux, Inc., 7101 College Blvd., suite 610, Overland Park, KS 66210, filed NADA 141–042 to provide for intramuscular use of the injectable drug product Immiticide Sterile Powder which consists of a vial of lyophilized powder containing 50 milligrams of melarsomine dihydrochloride to be reconstituted with the provided 2 milliliters of sterile water. The drug is indicated for the treatment of stabilized, class 1, 2, and 3 heartworm disease (asymptomatic to mild, moderate, and severe, respectively) caused by immature (4 month-old, stage L_5) to mature adult infections of *Dirofilaria immitis* in dogs. The drug product is available by prescription. The NADA is approved as of July 21, 1995, and the regulations are amended in part 522 (21 CFR part 522) by adding new § 522.1362 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning July 21, 1995, because no active ingredient

(including any ester or salt of the active ingredient) has been approved in any other application under section 512(b)(1) of the act.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. New § 522.1362 is added to read as follows:

§ 522.1362 Melarsomine dihydrochloride for injection.

(a) *Specifications.* The drug consists of a vial of lyophilized powder containing 50 milligrams of melarsomine dihydrochloride which is reconstituted with the provided 2 milliliters of sterile water for injection.

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* For asymptomatic to moderate (class 1 to class 2) heartworm disease: 2.5 milligrams per kilogram of body weight (1.1 milligram per pound) twice, 24 hours apart. The series can be repeated in 4 months depending on the response to the first treatment and the condition, age, and use of the dog. For severe (class 3) heartworm disease: Single injection of 2.5 milligrams per kilogram followed, approximately 1 month later, by 2.5 milligrams per kilogram administered twice, 24 hours apart.

(2) *Indications.* Treatment of stabilized, class 1, 2, and 3 heartworm disease (asymptomatic to mild, moderate, and severe, respectively) caused by immature (4 month-old, stage L_5) to mature adult infections of *Dirofilaria immitis* in dogs.

(3) *Limitations.* Administer only by deep intramuscular injection in the lumbar muscles (L_3-L_5). Use a 23 gauge 1 inch needle for dogs less than or equal to 10 kilograms (22 pounds) and a 22 gauge 1 1/2 inch needle for dogs greater than 10 kilograms (22 pounds). Use alternate sides with each administration. The drug is contraindicated in dogs with class 4 (very severe) heartworm disease (Caval Sydrome). Not for use in breeding animals and lactating or pregnant bitches. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: September 1, 1995.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 95–23603 Filed 9–22–95; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[MO–21–1–6443(a); FRL–5289–6]

Approval and Promulgation of Implementation Plans and Delegation of 112(l) Authority; State of Missouri

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: Missouri submitted its Rule 10 CSR 10–6.065, entitled ''Operating Permits,'' for Federal approval. The rule would establish a mechanism for creating federally enforceable limitations that would reduce sources' potential to emit such that sources could avoid major source permitting requirements. This action approves this rule as satisfying the criteria set forth in the Federal Register of June 28, 1989, for EPA approval of federally enforceable state operating permit programs (FESOP). In addition, this action addresses Missouri's program covering both criteria pollutants (regulated under section 110 of the Clean Air Act (CAA)) and hazardous air pollutants (HAP) (regulated under section 112).

DATES: This final rule is effective November 24, 1995, unless by October 25, 1995 adverse or critical comments are received.

ADDRESSES: Written comments should be addressed to: Joshua A. Tapp, Air Planning and Development Section, United States Environmental Protection Agency, 726 Minnesota Avenue, Kansas City, Kansas 66101.

Copies of the State Implementation Plan (SIP) revision request and EPA's analysis are available for public inspection during normal business hours at the following address: United States Environmental Protection Agency, Region VII, Air and Toxics Division, 726 Minnesota Avenue, Kansas City Kansas 66101.

FOR FURTHER INFORMATION CONTACT: Joshua A. Tapp, Air Planning and Development Section, United States Environmental Protection Agency, Region VII, Kansas City, Kansas 66101 ((913) 551–7606).

SUPPLEMENTARY INFORMATION:

I. Review of State Submittal

For many years, Missouri has been issuing permits for major new sources and for major modifications of existing sources. Throughout this time, Missouri has also been issuing permits establishing limitations on the potential emissions from new sources so as to avoid major source permitting requirements. This latter type of permitting has been the subject of various guidance from EPA, most notably the memorandum entitled ''Guidance on Limiting Potential to Emit in New Source Permitting'' dated June 13, 1989.

The operating permit provisions in title V of the Clean Air Act Amendments of 1990 have created interest in mechanisms for limiting sources' potential-to-emit, thereby allowing the sources to avoid being defined as ''major'' with respect to title V operating permit programs. A key mechanism for such limitations is the use of FESOPs. EPA issued guidance on FESOPs in the Federal Register of June 28, 1989 (54 FR 27274). On April 6, 1994, Missouri submitted its newly adopted rule 10 CSR 10–6.065 to provide for FESOPs in Missouri. This rule would supplement the preexisting mechanism for establishing federally enforceable limitations on potential-to-emit (i.e., new source permits). This document evaluates whether Missouri has satisfied the requirements for this type of federally enforceable limitation on potential-to-emit.

As specified in the Federal Register of June 28, 1989, the first provision necessary for an FESOP program is that the state must have approved operating permit regulations. Rule 10 CSR 10–6.065 sections 1, 2, 3, 4(C)-(P), 5, and 7 serve as the foundation for the FESOP rule and the rule defines the ''intermediate'' permitting program. EPA approval of the program will satisfy the first provision for Federal enforceability.